Vanguard MedReview, Inc.
4604 Timken Trail
Fort Worth, TX 76137
P 817-751-1632
F 817-632-2619

May 31, 2016

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
1 Bilateral Transforaminal Cervical Epidural Steroid Injection at C4-C5 under Anesthesia with Fluoroscopic Guidance and Epidurogram between 4/29/2016 and 6/28/2016

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This case was reviewed by a Board Certified Doctor of Anesthesiology with over 10 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male X who sustained injury when he hit his head on XXXXXX after he stood up from a kneeling position.

XX/XX/XX: MRI Cervical Spine w/o contrast. **Impression:** Degenerative spondylosis present with broad-based bulging of the disc at C3-C4 with lateralization towards the left with spinal stenosis and left lateral recess and left neural foraminal narrowing noted. The size of the disc bulge at this level measured on the T2 axial image sequence measures 3.8mm

XX/XX/XX: Procedure Note. **Pre-op Diagnosis:** Cervicalgia, Displacement of cervical intervertebral disc, Cervical radiculopathy, Neuritis and/or radiculitis due to displacement of cervical intervertebral disc. **Procedure:** Transformainal ESI- Cervical, single, bilateral. Transforminal ESI-Cervical, each additional bilateral. Epidurogram/Neurogram. Fluoro Guidance/Localization of needle or catheter.

XX/XX/XX: Office Visit. **Subjective:** XX is here for f/u. He is complaining of increased neck pain. He received his initial cervical ESI on XX/XX/XX and had significant improvement. He has since gone through court with XXXXXXX and stated that he saw a designated doctor who is also ordered a second ESI. Patient is currently taking tramadol, zanaflex, and ibuprofen which she states is helping as well. We will order the second ESI to occur at C4 and C5 bilaterally. **General:** Neck is supple without lymphadenopathy. Tenderness to palpation across the cervical region with bilateral hypertonicity of the paraspinal musculatures. ROM for the cervical spine is moderately decreased in

all planes. Cervical compression test reproduces slight pain with radiculopathy. Reflexes are within normal limits for the upper extremity with the exception of C7 shows a +1/2 reflex where normal is 2/2. Manual muscle testing was within normal limits. **Plan:** ESI procedure requested.

XX/XX/XX: UR. **Rationale for Denial:** Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced below, this request is non-certified. Guidelines do not recommend cervical epidural steroid injections based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. Also, there was no documented functional response from the previous cervical epidural steroid injection including decreased pain medication used and increased activities of daily living.

XX/XX/XX: Letter of Reconsideration. XX had greater than 50% pain relief from his first injection and that was several months ago. This pain relief has lasted for approximately 8 weeks. He should meet criteria for a second injection.

XX/XX/XX: UR. **Rationale for Denial:** Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines this request is non-certified. The most recent medical records submitted on XX/XX/XX had no documentation of objective findings of functional improvement that would support the provider's claim. There was no documentation of decreased pain medication used and increased activities of daily living. In addition, per guidelines, ESIs are not recommended for higher than the C6-7 level. Thus, the request is not medically established.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines this request is non-certified. Medical records submitted on XX/XX/XX had no documentation of objective findings of functional improvement that would support the provider's claim. There was no documentation of decreased pain medication used and increased activities of daily living. In addition, per guidelines, ESIs are not recommended for higher than the C6-7 level. Thus, the request is not medically established.

Per ODG:

Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. These had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below. In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and also one year in individuals with radiating chronic neck pain. (Peloso-*Cochrane*, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) The American Academy of Neurology concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open

surgery. (Haldeman, 2008) (Benyamin, 2009) Some have said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-*Cochrane*, 2006) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014)
Recent evidence: ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia, spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the cervical region, as opposed to the lumbar area, are relatively risky, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; & particulate steroids should not be used in therapeutic cervical transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014) See the Low Back Chapter, where ESIs are recommended as a possible option for short-term treatment of radicular pain in conjunction with active rehab efforts, but they are not recommended for spinal stenosis or for nonspecific low back pain.

While not recommended, cervical ESIs may be supported using Appendix D, Documenting Exceptions to the Guidelines, in which case:
Criteria for the use of Epidural steroid injections, therapeutic:
Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.
(1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.
(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
(3) Injections should be performed using fluoroscopy (live x-ray) for guidance
(4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.
(5) No more than two nerve root levels should be injected using transforaminal blocks.
(6) No more than one interlaminar level should be injected at one session.
(7) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.
(8) Repeat injections should be based on continued objective documented pain and function response.
(9) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.
(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
(11) Cervical and lumbar epidural steroid injection should not be performed on the same day;
(12) Additional criteria based on evidence of risk:
    (a) ESIs are not recommended higher than the C6-7 level;
    (b) Cervical interlaminar ESI is not recommended; &
    (c) Particulate steroids should not be used. (Benzon, 2015)

Criteria for the use of Epidural steroid injections, diagnostic:
To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:
(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;
(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g. dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;
(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**